

## Environmental Protection Agency

## §§ 158.1500–158.1900

6. Required when a pesticide is to be applied directly to livestock, to livestock premises, to livestock drinking water, or to crops used for livestock feed. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock metabolism study involving dosing with the plant metabolite(s) may also be required.

7. Required when the Agency determines that it is reasonably foreseeable that a food or feed crop could be subsequently planted on the site of pesticide application after harvest or failure of the treated crop. Typically not required for pesticide uses in permanent food crops (e.g., various tree crops, vines) or semi-permanent crops (e.g., asparagus, pineapples).

8. A residue analytical method suitable for enforcement purposes is required whenever a numeric tolerance (including temporary and time-limited tolerances) is proposed.

9. New analytical methods to be used for enforcement purposes must include results from an independent laboratory validation.

10. A residue method, storage stability data, and crop field trials are required for the nonfood crop tobacco (green, freshly harvested). Depending on the level of residues found on the green tobacco, additional data may be required on cured/dried tobacco and pyrolysis products.

11. Data are required to determine whether FDA/USDA multiresidue methodology would detect and identify the pesticides and any metabolites.

12. Data are required for any magnitude of the residue study unless analytical samples are stored frozen for 30 days or less, and the active ingredient is not known to be volatile or labile.

13. Studies using single serving samples of a raw agricultural commodity may be needed for acutely toxic pesticides and/or their metabolites. These residue studies must be conducted using a statistical design accepted by the Agency.

14. Required for indoor uses which are direct postharvest treatments of raw agricultural commodities (e.g., fungicidal waxes or stored grain fumigants).

15. Data on the nature and level of residues in processed food/feed are required if residues could potentially concentrate on processing thus requiring the establishment of a separate tolerance higher than that of the raw agricultural commodity.

16. Required when the pesticide use is a direct application to livestock.

17. Data are required if pesticide residues are present in or on livestock feed items or intentionally added to drinking water. These studies, however, may not be required in cases where the livestock metabolism studies indicate negligible transfer of the pesticide's residues of concern to tissues, milk,

and eggs at the maximum expected exposure level for the animals.

18. If results from the plant metabolism study show differing metabolites in plants from those found in animals, an additional livestock feeding study involving dosing with the plant metabolite(s) may also be required.

19. Data are required whenever a pesticide may be applied directly to water, unless it can be demonstrated that the treated water would not be available for human or livestock consumption.

20. Data are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.

21. Data are required whenever a pesticide may be used in a food handling or feed handling establishment.

22. Required when residues at the tolerance level may result in a risk of concern. These data may include washing, cooking, processing or degradation studies as well as market basket surveys for a more precise residue determination.

23. Typically required if pesticide residues of concern greater than 0.01 ppm are found in crops at the appropriate plant back intervals (taking into account plant back restrictions on product labels) in the confined rotational crop study. If residues of concern in the confined study are greater than 0.01 ppm but less than the limit of quantitation of the analytical method to be used on field trial samples, the Agency will consider not requiring, on a case-by-case basis, the limited field trials. If there are particular toxicological concerns with the parent pesticide or any metabolites, limited field studies may be needed if such residues are identified at levels below 0.01 ppm in the confined study.

24. Crop field trials are required to establish tolerances on rotational crops when quantifiable residues of concern are observed in the field rotational crops study.

25. Not required for an exemption from a tolerance provided that dietary exposure estimates are not needed due to low toxicity or that theoretical estimates of exposure are adequate to assess dietary risk.

26. Not required for an exemption from a tolerance.

### Subparts P–T [Reserved]

### §§ 158.1500–158.1900 [Reserved]

### Subpart U—Biochemical Pesticides

SOURCE: 72 FR 61002, Oct. 26, 2007, unless otherwise noted.